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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0529]

Secura Bio, Inc.; Withdrawal of Approval of Relapsed or Refractory Follicular Lymphoma Indication for COPIKTRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is withdrawing approval of the relapsed or refractory follicular lymphoma indication for COPIKTRA (duvelisib) Capsules, approved under new drug application 211155, held by Secura Bio, Inc., 1995 Village Center Circle, Suite 128, Las Vegas, NV 89134. Secura Bio, Inc. voluntarily requested that the Agency withdraw approval of this indication and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA approved COPIKTRA (duvelisib) Capsules for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies (the follicular lymphoma indication) on September 24, 2018, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of COPIKTRA (duvelisib) Capsules for follicular lymphoma, the applicant was required to conduct a postmarketing trial to verify the clinical benefit of duvelisib for follicular lymphoma.

On November 22, 2021, FDA met with Secura Bio, Inc., to discuss the company's inability to conduct a clinical trial to verify clinical benefit of duvelisib in follicular lymphoma. Because the confirmatory trial was not underway and would not be conducted, the Agency recommended withdrawal of approval of the follicular lymphoma indication pursuant to § 314.150(d) (21 CFR 314.150(d)). On November 24, 2021, Secura Bio, Inc. submitted a letter requesting withdrawal of approval of the follicular lymphoma indication for COPIKTRA (duvelisib) Capsules and waiving its opportunity for hearing.

Therefore, under § 314.150(d), approval of the follicular lymphoma indication for COPIKTRA (duvelisib) Capsules is withdrawn effective [INSERT DATE OF PUBLICATION]. Withdrawal of approval of the follicular lymphoma indication does not affect any other approved indication for COPIKTRA.

Dated: April 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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